

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Claim 1 (currently amended): A stent having a coating comprising:

- (a) a primer layer having a polymer composition of two or more polymers, and
- (b) an a single outermost drug reservoir layer having a polymer composition of two or more polymers comprising a drug stabilizing polymer, the primer layer polymer composition polymers being distinct from the drug reservoir layer polymer composition polymers, the drug reservoir layer further comprising one or more active agents, the drug reservoir layer protecting and stabilizing the one or more active agents during sterilization and storage,

the coating having sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, and releasing efficacious amounts of the active agent at the site of stent expansion.

Claim 2 (currently amended): The stent of claim 1, further comprising an intermediate layer between the primer layer and the drug reservoir layer, comprising a polymer composition distinct from the primer layer polymer composition and the drug reservoir layer polymer composition first and second compositions.

Claim 3 (previously presented): The stent of claim 1, further comprising one or more image enhancing material(s) in one of the layers, or in a separate layer(s), that is capable of enhancing visibility in ultra sound, magnetic resonance imaging, or X ray imaging.

Claim 4 (currently amended): The stent of claim 1, wherein the primer layer and/or the drug reservoir layer is a single layer.

Claim 5 (previously presented): The stent of claim 49, wherein the anchoring polymers have functional groups, selected from amides, carboxyl, hydroxyl, amine, imine, amide, imide, sulfoxyl, sulfonyl, and combinations.

Claim 6 (original): The stent of claim 1, wherein the primer layer further comprises one or more cross-linking and/or cross-linkable polymers selected from epoxy resins, melamine resins, phenolics, and isocyanate polymers.

Claim 7 (original): The stent of claim 1, wherein the primer layer further comprises one or more of polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA), olefin acrylic acid copolymer, polyethylene glycol, polyethylene oxide, and polyvinylpyridine polymers and copolymers.

Claim 8 (original): The stent of claim 1, wherein the stabilizing polymer is a cellulose ester, a cellulose ether, an acrylic polymer and/or an acrylic copolymer.

Claim 9 (previously presented): The stent of claim 50, wherein the toughening polymer is a polyurethane.

Claim 10 (previously presented): The stent of claim 1 wherein the drug reservoir layer further includes a relatively hydrophilic polymer selected from the group consisting of hydroxyethyl methacrylate (HEMA), copolymers of HEMA with acrylate, copolymers of HEMA with polymethylmethacrylate (PMMA), polyvinyl pyrrolidone, polyvinylpyrrolidone/vinyl acetate copolymers (PVP/VA), polyethylene glycols, and polyethylene oxides.

Claim 11 (original): The stent of claim 1 comprising more than one active agent.

Claim 12 (original) The stent of claim 1 in which the primer layer comprises one or more polymers selected from the group consisting of acrylate polymer/copolymer, acrylate carboxyl and/or hydroxyl copolymer, olefin acrylic acid copolymer, ethylene acrylic acid copolymer, polyamide polymers/copolymers polyimide polymers/copolymers, and/or polyether sulfones.

Claim 13 (original): The stent of claim 1 in which the primer layer comprises one or more polymers selected from the group consisting of ethylene vinylacetate copolymer, acrylate polymer/copolymer, acrylate carboxyl and/or hydroxyl copolymer, olefin acrylic acid copolymer, ethylene acrylic acid copolymer, polyamide polymers/copolymers polyimide polymers/copolymers, and/or polyether sulfones.

Claim 14 (original): The stent of claim 2, wherein the intermediate layer comprises one or more polymers selected from the group consisting of acrylate polymer/copolymer, acrylate carboxyl and/or hydroxyl, polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA), polyurethane, silicone urethane polymer, polycarbonate urethane polymer, polyvinylbutyral, and/or epoxy polymers.

Claim 15 (original): The stent of claim 1, wherein the primer and/or drug reservoir layer comprises one or more polymer selected from the group consisting of polyurethane, polycarbonate urethane polymer, and silicone urethane polymer.

Claim 16 (original): The stent of claim 1 comprising one or more polymers having a flexural modulus greater than 1000 psi and elongation at break greater than 200%.

Claim 17 (original): The stent of claim 1 having a drug reservoir layer comprising a polymer selected from acrylate polymer/copolymer, acrylate hydroxyl and/or carboxyl copolymer, polyvinyl pyrrolidone (PVP), polyvinylpyrrolidone/vinyl acetate copolymer (PVP/VA), cellulose ester, polyurethane, polycarbonate-urethane polymer, silicone-urethane polymer, epoxy polymer, polyethylene glycol and/or polyethylene oxide.

Claim 18 (original): The stent of claim 1 having a drug reservoir layer comprising one or more polyurethanes, and one or more cellulose ester polymers.

Claim 19 (original): The stent of claim 1 having a drug reservoir layer comprising one or more polymers selected from acrylate polymer/copolymer, acrylate polymer/copolymer containing carboxyl and/or hydroxyl groups, cellulose nitrate and/or other cellulose ester.

Claim 20 (original): The stent of claim 1 wherein the active agent comprises an anti-restenotic agent effective at a stented site.

Claim 21 (original): The stent of claim 1 having a total coating thickness between about 0.3 and about 30 microns.

Claim 22 (previously presented): The stent of claim 1 the primer layer having a thickness between about 0.1 and about 5 microns, and the drug reservoir layer having a thickness of between about 0.1 and about 10 microns.

Claim 23 (original): The stent of claim 2 the intermediate layer having a thickness between about 0.1 and about 15 microns.

Claim 24 (original): The stent of claim 1 wherein the active agent is selected from one or more of anti-thrombogenic agents, anti-inflammatory agents, antineoplastic agents, anti-proliferative agents, cytostatic agents, cytotoxic agents, antimicrobial agents, anti-restenotic agents, anti-platelet agents, and anti-coagulant agents.

Claim 25 (original): The stent of claim 1 wherein the active agent is selected from one or more of anti-fibrin and fibrinolytic agents, anti-platelet agents, prostacyclins (and analogues), glycoprotein IIb/IIIa agents, thromboxane inhibitors, anti-thrombin and anti-coagulant agents, anti-mitotic, antiproliferative and cytostatic agents, antiangiogenic and angiostatic agents, ACE inhibitors, growth factor antagonists, antioxidants, vitamins, calcium channel blockers, fish oil (omega 3-fatty acid), phosphodiesterase inhibitors, nitric acid donor, Somatostatin analogues, immunosuppressive agents, antiinflammatory agents, antimicrobials, radionuclides including alpha, beta and gamma emitting isotopes, COX-2 inhibitors, endothelial promoters, kinase inhibitors, epidermal growth factor kinase inhibitors, tyrosine kinase inhibitors, MAP kinase inhibitors, and protein transferase inhibitors.

Claim 26 (currently amended): The stent of claim 1 wherein the active agent is selected from one or more of plasmin, streptokinase, single chain urokinase, urokinase, t-PA (tissue type plasminogen activator), aminocaproic acid, aspirin, monoclonal antibodies, peptides, ReoPro, Cilastagel, eptifibatide, tirofiban, ticlopidine, Vapiprost, dipyridamole, forskolin, angiopoetin, argatroban, dextan, heparin, LMW heparin, heparin complexes, Enoxaparin, Dalteparin, hirudin, recombinant hirudin, anti-thrombin, synthetic antithrombins, thrombin inhibitors, Warfarin, other coumarins, vincristine, vinblastine, paclitaxel or a paclitaxel analogue and its analogues, methotrexate, cisplatin, fluorouracil, rapamycin, azathioprine, cyclophosphamide, mycophenolic acid, corticosteroids, colchicine, nitroprusside, ~~paclitaxel~~, angiostatin and endostatin; genetic materials, oligonucleotides, Cilazapril, Lisinopril, Captopril, VEGF, FGF, Probulcol, Tocopherol, nifedipine, dipyridamole, Molsidomine, angiopoetin, prednisolone, glucocorticoid, dexamethasone, rifamycin, Re-188, Re-186, I-125, Y-90 celecoxib, Viox, dipyridamole, and theophylline.

Claim 27 (previously presented): The stent of claim 1 wherein the active agent is selected from one or more of tacrolimus, everolimus, and sirolimus.

Claim 28 (original): The stent of claim 1 wherein the primer layer comprises one or more of acrylate/carboxyl polymer, epoxy polymer, polyvinylpyrrolidone vinylacetate copolymer (PVP/VA).

Claim 29 (original): The stent of claim 1 wherein the primer layer comprises one or more of ethylene acrylic acid copolymer (EAA), epoxy polymer, and polycarbonate urethane.

Claim 30 (original): The stent of claim 2 wherein the intermediate layer comprises polycarbonate polyurethane.

Claim 31 (original): The stent of claim 1 wherein the drug reservoir layer comprises one or more of acrylate/carboxyl polymer, epoxy polymer, and polyvinylpyrrolidone vinylacetate copolymer (PVP/VA).

Claim 32 (previously presented): The stent of claim 1 wherein the drug reservoir layer comprises nitrocellulose.

Claim 33 (previously presented): The stent of claim 1 wherein the drug reservoir layer comprises nitrocellulose and one or more of polytetramethylene ether glycol urethane, polycarbonate-urethane, silicone-urethane polymer, polyethylene glycol, polymethylmethacrylate-2-hydroxyethylmethacrylate copolymer, polyethylmethacrylate-2-hydroxyethylmethacrylate copolymer, polypropylmethacrylate-2-hydroxyethylmethacrylate copolymer, polybutylmethacrylate-2-hydroxyethylmethacrylate copolymer, polymethylacrylate-2-hydroxyethylmethacrylate copolymer, polyethylacrylate-2-hydroxyethylmethacrylate copolymer, polypropylacrylate-2-hydroxymethacrylate copolymer, polybutylacrylate-2-hydroxyethylmethacrylate copolymer, copolymermethylvinylether maleicanhydride copolymer, and poly (2-hydroxyethyl methacrylate).

Claim 34 (previously presented): The stent of claim 1, wherein the drug reservoir layer comprises an ionic heparin complex, and at least one other bioactive agent that is not anti-thrombogenic.

Claim 35 (original): The stent of claim 1, wherein one of the agents is an ionic complex of heparin, and at least one more agent is present that is selected from the group consisting of an anti-angiogenic factor, an immunosuppressing agent, an antimicrobial agent, an anti-inflammatory agent, an anti-restenotic agent and combinations.

Claim 36 (original): The stent of claim 1, wherein the active agent comprises heparin together with at least one of an anti-restenotic drug selected from the group consisting of paclitaxel, rapamycin, sirolimus, everolimus, tacrolimus, and combinations.

Claim 37 (original): The stent of claim 1 wherein the active agent is selected from the group consisting of paclitaxel, heparin complexes, rifamycin, methotrexate, and combinations.

Claim 38 (previously presented): The stent of claim 1, wherein the active agents are benzalkonium heparinate and paclitaxel.

Claim 39 (original): The stent of claim 1, wherein the primer layer comprises an ethylene acrylic acid copolymer and an epoxy polymer.

Claim 40 (previously presented): The stent of claim 39, wherein the ethylene acrylic acid copolymer is one or more of PRIMACOR 5989 and 5990.

Claim 41 (previously presented): The stent of claim 39, wherein the epoxy is one or more of EPOTUF 38-505, EPOTUF 37-618, and EPON 1001.

Claim 42 (original): The stent of claim 1, wherein the drug reservoir layer comprises a polyurethane and a cellulose nitrate.

Claim 43 (original): The stent of claim 42, wherein the polyurethane is polytetramethylene ether glycol urethane and/or polycarbonate urethane.

Claim 44 (previously presented) The stent of claim 42 wherein the polyurethane is selected from the group consisting of CHRONOFLEX AR, CHRONOFLEX AL, CHRONOFLEX C and BIONATE 80A.

Claim 45 (previously presented): The stent of claim 42 wherein the polyurethane is CHRONOFLEX AR.

Claim 46 (original): The stent of claim 1, wherein the primer layer comprises an ethylene acrylic acid copolymer and an epoxy polymer and the drug reservoir layer comprises a polyurethane and a cellulose ester.

Claim 47 (currently amended): A stent comprising:

a stent body,

a single outermost drug reservoir layer comprising a biologically active agent,

means for containing and controllably releasing the agent from the stent over an extended period, comprising a means for stabilizing the active agent, comprising a stabilizing polymer and means for strengthening the containing means, comprising a toughening polymer, and

means for anchoring the containing means to the stent body, comprising an anchoring a-second polymer,

the containing and anchoring means remaining intact upon stent expansion and during the extended period,

wherein said containing and controllably releasing means is distinct from said anchoring means.

Claim 48 (cancelled)

Claim 49 (previously presented): The stent of claim 1, wherein the primer layer comprises an anchoring polymer.

Claim 50 (previously presented): The stent of claim 1, wherein the drug reservoir layer further comprises a toughening polymer.

Claim 51 (previously presented): The stent of claim 1, wherein the drug reservoir layer forms a hybrid polymer matrix.

Claim 52 (previously presented): The stent of claim 1, wherein the coating remains intact upon insertion and stent expansion in a subject.

Claim 53 (new) The stent of claim 1 wherein the active agent comprises an anti-platelet agent and an anti-proliferative agent or a cytostatic agent.

Claim 55 (new) The stent of claim 1 wherein the active agent comprises an anti-platelet agent and an anti-angiogenic agent or an angiostatic agent.

Claim 56 (new) The stent of claim 1 wherein the active agent comprises dipyridamole and paclitaxel or a paclitaxel analogue.

Claim 57 (new) The stent of claim 1 wherein the active agent comprises paclitaxel or a paclitaxel analogue.

Claim 58 (new) The stent of claim 1, further comprising one or more drug reservoir layers.

Claim 59 (new): A stent having a coating comprising:

- (a) a primer layer having a hybrid polymer composition of at least one hydrophobic polymer and at least one hydrophilic polymer, the primer layer including an anchoring polymer having a functional group selected from the group

consisting of amides, carboxyl, hydroxyl, amine, imine, amide, imide, sulfoxyl, sulfonyl, and combinations, and

(b) a single outermost drug reservoir layer having a hybrid polymer composition of at least one hydrophobic polymer and at least one hydrophilic polymer, the drug reservoir layer including a drug stabilizing polymer, a toughening polymer and one or more active agents, the primer layer polymer composition being distinct from the drug reservoir layer polymer composition, the drug reservoir layer protecting and stabilizing the one or more active agents during sterilization and storage,

the coating having sufficient adhesion and flexibility to remain intact upon stent expansion and during a sustained period thereafter, and releasing efficacious amounts of the active agent at the site of stent expansion.